

REMARKS

Claims 19-40 are pending in the present application, with claims 21-37 having been withdrawn from further consideration. By the present Communication, claims 38 and 39 have been canceled, new claims 41-47 have been added, and claims 19 and 40 have been amended to define Applicant's invention with greater particularity. Support for the added and amended claim language may be found, among others, at page 22, line 10 to page 23, line 8; page 23, lines 9-13; page 24, lines 1-6; page 26, lines 3-8; and page 26, lines 9-11, of the specification as filed. Accordingly, claims 19, 20, 38, and 40-46 will be under consideration.

Objections to the Specification

Applicants respectfully traverse the objection to the title as allegedly not being descriptive of the claimed invention. Without acquiescing to the reasoning offered by the Office, and in order to expedite prosecution of the instant application, Applicants have amended the title to better describe the claimed invention. Withdrawal of the objection is respectfully requested.

Information Disclosure Statement

The Office alleges that the information disclosure statement filed on November 24, 2003, fails to comply with the provisions of 37 C.F.R. §§1.97-1.98 because the IDS has already been signed by someone else who is not the current examiner. Attached herewith is a resubmission of the IDS on a new form PTO/SB/08 1449 for consideration by the Examiner.

Rejections under 35 U.S.C. §101

Applicants respectfully traverse the rejection of claims 19 and 38-40 under 35 U.S.C. §101, as allegedly being directed to non-statutory subject matter. Applicants have canceled claims 38 and 39, rendering the rejection moot as to those claims. Without acquiescing to the reasoning offered by the Office, and in order to expedite prosecution of the instant application, Applicants have amended claim 19 to recited an "isolated" antibody. As such, Applicants submit

that the claimed subject matter reflects the “hand of man,” and respectfully request withdrawal of the rejection.

Rejections under 35 U.S.C. §112, First Paragraph

Applicants respectfully traverse the rejection of claims 19, 20 and 38-40 under 35 U.S.C. §112, first paragraph, as allegedly failing to comply with the written description requirement. Applicants have canceled claims 38 and 39, rendering the rejection moot as to those claims. Without acquiescing to the reasoning offered by the Office, and in order to expedite prosecution of the instant application, Applicants have amended claim 19 to recite that the FHF-4 polypeptide comprises the amino acid sequence as set forth in SEQ ID NO: 4 or SEQ ID NO: 11. As such, Applicants submit that the FHF-4 polypeptide is defined by structure, and respectfully request withdrawal of the rejection.

Rejections under 35 U.S.C. §112, Second Paragraph

Applicants respectfully traverse the rejection of claims 19, 20 and 38-40 under 35 U.S.C. §112, second paragraph, as allegedly failing to particularly point out and distinctly claim the subject matter which applicant regards as the invention. Applicants have canceled claims 38 and 39, rendering the rejection moot as to those claims. Without acquiescing to the reasoning offered by the Office, and in order to expedite prosecution of the instant application, Applicants have amended claim 19 to remove the term “substantially pure,” which is allegedly a relative term. Applicants submit that the claimed invention is distinctly claimed, and respectfully request withdrawal of the rejection.

Rejections under 35 U.S.C. §102

Applicants respectfully traverse the rejection of claims 19 and 38-40 under 35 U.S.C. §102(b), as allegedly being anticipated by Patry, et al. (FEBS Letters, 349:23-28 1994; hereinafter, “Patry”). To anticipate, a single reference must inherently or expressly teach each and every element of claimed invention. *In re Spada*, 15 USPQ2d 1655 (Fed Cir. 1990); and

Verdegaal Bros. v. Union Oil Co. of California, 2 USPQ2d 1051, 1053 (Fed. Cir. 1987). MPEP § 2131.

The Office Action alleges that Patry teaches high and low molecular weight forms of FGF-2, which “appear to meet the description of FHF-4 proteins as characterized in the claims, assuming about 225-250.” (Office Action, page 9). Applicants have canceled claims 38 and 39, rendering the rejection moot as to those claims. Without acquiescing to the reasoning offered by the Office, and in order to expedite prosecution of the instant application, Applicants have amended claim 19 to recite that the FHF-4 polypeptide comprises the amino acid sequence as set forth in SEQ ID NO: 4 or SEQ ID NO: 11. Applicants respectfully submit that Patry is absolutely silent with regard to an FHF-4 polypeptide comprising the amino acid sequence as set forth in SEQ ID NO: 4 or SEQ ID NO: 11. More specifically, Patry does not disclose an antibody that specifically binds to a fibroblast growth factor homologous factor-4 (FHF-4) polypeptide, wherein the FHF-4 polypeptide comprises the amino acid sequence as set forth in SEQ ID NO: 4 or SEQ ID NO: 11. Accordingly, since Patry fails to teach each and every limitation of the claims as amended, Applicants respectfully submit that Patry fails to anticipate the claimed invention, and request withdrawal of the rejection.

Applicants respectfully traverse the rejection of claims 19, 20, and 38-40 under 35 U.S.C. §102(e), as allegedly being anticipated by Greene, et al. (U.S. Pat. No. 6,482,408; hereinafter, “Greene”). To anticipate, a single reference must inherently or expressly teach each and every element of claimed invention. *In re Spada*, 15 USPQ2d 1655 (Fed Cir. 1990); and *Verdegaal Bros. v. Union Oil Co. of California*, 2 USPQ2d 1051, 1053 (Fed. Cir. 1987). MPEP § 2131.

The Office Action alleges that Greene discloses FGF-15, which has at least 117 consecutive residues that are identical with SEQ ID NO: 4 of the instant invention. According to the Action, the antibodies of Green would inherently bind SEQ ID NO: 4 of FHF-4. Applicants have canceled claims 38 and 39, rendering the rejection moot as to those claims. Without acquiescing to the reasoning offered by the Office, and in order to expedite prosecution of the instant application, Applicants have amended claim 19 to recite that the antibody specifically binds to a fibroblast growth factor homologous factor-4 (FHF-4) polypeptide, wherein the FHF-4

polypeptide comprises the amino acid sequence as set forth in SEQ ID NO: 4 or SEQ ID NO: 11. Applicants submit that Greene is absolutely silent with regard to an FHF-4 polypeptide comprising the amino acid sequence as set forth in SEQ ID NO: 4 or SEQ ID NO: 11. More specifically, Greene does not disclose an antibody that specifically binds to a fibroblast growth factor homologous factor-4 (FHF-4) polypeptide, wherein the FHF-4 polypeptide comprises the amino acid sequence as set forth in SEQ ID NO: 4 or SEQ ID NO: 11.

The recent Federal Circuit opinion in *Schering Corp. v. Geneva Pharmaceuticals Inc.*, (339 F.3d 1373), while attempting to clarify two lines of divergent authority on the standard of inherent anticipation, has caused considerable controversy regarding the patentability of drug metabolites. *Schering* holds that a metabolite (compounds that are formed in a patient's body upon ingestion of the pharmaceutical product) is unpatentable if giving the drug to a patient *necessarily and inevitably* results in formation of that metabolite. (*Schering*, 339 F.3d at 1377-78). Applying the standard of anticipation by inherency, as promulgated by the Court in *Schering Corp. v. Geneva Pharmaceuticals Inc.*, Applicants respectfully submit that the antibody disclosed by Greene would not *necessarily and inevitably* bind to the FHF-4 polypeptide of SEQ ID NO: 4, as required by the amended claims, because the antibody of Green could bind to a region that is not conserved between the Greene polypeptide and SEQ ID NO: 4 of the instant application. If, for example, the 117 consecutive amino acids are hydrophobic, then there is a high likelihood that the conserved sequence will not be exposed to a hydrophilic environment, and therefore would likely not be selected as an epitope for antibody binding. As such, Applicants respectfully submit that Greene does not satisfy the standard of anticipation by inherency, as set forth in *Schering*.

Accordingly, since Greene fails to teach each and every limitation of the claims as amended, Applicants respectfully submit that Greene fails to anticipate the claimed invention, and request withdrawal of the rejection.

Applicants respectfully traverse the rejection of claims 19, 20, and 38-40 under 35 U.S.C. §102(e), as allegedly being anticipated by Nathans, et al. (U.S. Pat. No. 5,872,226; hereinafter, "Nathans"). To anticipate, a single reference must inherently or expressly teach each and every

element of claimed invention. *In re Spada*, 15 USPQ2d 1655 (Fed Cir. 1990); and *Verdegaal Bros. v. Union Oil Co. of California*, 2 USPQ2d 1051, 1053 (Fed. Cir. 1987). MPEP § 2131.

The Office Action alleges that Nathans discloses FHF-1, which “appears to meet the descript of FHF proteins as characterized in the claims, assuming about 225-250.” (Office Action, page 11). According to the Action, the antibodies of Green would inherently bind SEQ ID NO: 4 of FHF-4. Applicants have canceled claims 38 and 39, rendering the rejection moot as to those claims. Without acquiescing to the reasoning offered by the Office, and in order to expedite prosecution of the instant application, Applicants have amended claim 19 to recite that the antibody specifically binds to a fibroblast growth factor homologous factor-4 (FHF-4) polypeptide, wherein the FHF-4 polypeptide comprises the amino acid sequence as set forth in SEQ ID NO: 4 or SEQ ID NO: 11. Applicants submit that FHF protein disclosed by Nathans no longer appears to meet the description of the claimed antibody. Accordingly, since Nathans fails to teach each and every limitation of the claims as amended, Applicants respectfully submit that Nathans fails to anticipate the claimed invention, and request withdrawal of the rejection.

Applicants respectfully traverse the rejection of claims 19, 20, 38 and 40 under 35 U.S.C. §102(e), as allegedly being anticipated by Hu, et al. (U.S. Pat. No. 5,817,485; hereinafter, “Hu”). To anticipate, a single reference must inherently or expressly teach each and every element of claimed invention. *In re Spada*, 15 USPQ2d 1655 (Fed Cir. 1990); and *Verdegaal Bros. v. Union Oil Co. of California*, 2 USPQ2d 1051, 1053 (Fed. Cir. 1987). MPEP § 2131.

The Office Action alleges that Hu discloses FGF-10, which appears to meet “the description of FHF-4 polypeptides as characterized in the claim 38, assuming about 225-250.” (Office Action, page 11). Applicants have canceled claim 38, rendering the rejection moot as to that claim. Without acquiescing to the reasoning offered by the Office, and in order to expedite prosecution of the instant application, Applicants have amended claim 19 to recite that the antibody specifically binds to a fibroblast growth factor homologous factor-4 (FHF-4) polypeptide, wherein the FHF-4 polypeptide comprises the amino acid sequence as set forth in SEQ ID NO: 4 or SEQ ID NO: 11. Applicants submit that Hu is absolutely silent with regard to an FHF-4 polypeptide comprising the amino acid sequence as set forth in SEQ ID NO: 4 or SEQ

ID NO: 11. More specifically, Hu does not disclose an antibody that specifically binds to a fibroblast growth factor homologous factor-4 (FHF-4) polypeptide, wherein the FHF-4 polypeptide comprises the amino acid sequence as set forth in SEQ ID NO: 4 or SEQ ID NO: 11. Accordingly, since Hu fails to teach each and every limitation of the claims as amended, Applicants respectfully submit that Hu fails to anticipate the claimed invention, and request withdrawal of the rejection.


Conclusion

The Examiner is invited to contact Applicant's undersigned representative if there are any questions relating to this application.

The Commissioner is hereby authorized to charge \$300.00 as payment for the Petition for One-Month Extension of Time fee (\$120.00) and Information Disclosure Statement fee (\$180.00) to Deposit Account No. 07-1896. Additionally, the Commissioner is hereby authorized to charge any other fees that may be due in connection with the filing of this paper, or credit any overpayment to Deposit Account No. 07-1896, referencing the above-identified Attorney Docket number.

Respectfully submitted,

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